

FORM PTO-1390  
(REV. 01-2003)

US DEPARTMENT OF COMMERCE PATENT &amp; TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER  
125413**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**U.S. APPLICATION NO. (If known, see 37 CFR 1.5)  
10/549,510INTERNATIONAL APPLICATION NO.  
PCT/JP2004/004432INTERNATIONAL FILING DATE  
March 29, 2004PRIORITY DATE CLAIMED  
March 28, 2003TITLE OF INVENTION  
T-TYPE CALCIUM CHANNEL BLOCKERAPPLICANTS FOR DO/EO/US  
Yukinori MASUDA; Taiji FURUKAWA

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
  - c. ☐ The International Application was filed in English.
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☐ Other items or information:

U.S. APPLICATION NO. (if known, see 37 C.F.R. 1.5) 10/549,510		INTERNATIONAL APPLICATION NO. PCT/JP2004/004432		ATTORNEY'S DOCKET NUMBER 125413	
21. <input type="checkbox"/> The following fees are submitted:				<b>CALCULATIONS</b>	
				<b>PTO USE ONLY</b>	
<b>BASIC NATIONAL FEE (37 CFR 1.492(a)):</b> ..... \$ 300.00				\$	
<b>SEARCH FEE (37 CFR 1.492(b)(1)-(3)):</b>				\$	
International preliminary examination report or written opinion prepared by the USPTO as IPEA or ISA and favorable as to novelty, inventive step, and industrial applicability for all claims presented in the application entering the national stage ..... \$ 0.00					
International search fee (37 CFR 1.445(a)(2)) paid to USPTO as ISA ..... \$ 100.00					
International search report provided to USPTO no later than the time at which the search fee is paid ..... \$ 400.00					
All situations not provided for above ..... \$ 500.00					
<b>EXAMINATION FEE (37 CFR 1.492(c)(1)-(2)):</b>				\$	
International preliminary examination report or written opinion prepared by the USPTO as IPEA or ISA and favorable as to novelty, inventive step, and industrial applicability for all claims presented in the application entering the national stage ..... \$ 0.00					
All situations not provided for above ..... \$ 200.00					
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
TOTAL PAGES OF APPLICATION OVER 100 ( - 100)	+ 50	= †	x 250 =	\$	
†round up to next integer					
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
TOTAL CLAIMS	- 20	=	x 50.00 =	\$	
INDEPENDENT CLAIMS	- 3	=	x 200.00 =	\$	
MULTIPLE DEPENDENT CLAIM(S)(if applicable)			+ 360.00 =	\$	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by ½.				\$	
<b>SUBTOTAL =</b>				\$	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	
<b>TOTAL NATIONAL FEE =</b>				\$	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$	
<b>TOTAL FEES ENCLOSED =</b>				\$	
				Amount to be refunded:	\$
				charged:	\$
a. <input type="checkbox"/> Check No. _____ in the amount of \$_____ to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$_____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>15-0461</u> . A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. <b>Credit card information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038.					
<b>NOTE:</b> Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO: OLIFF & BERRIDGE, PLC Customer Number: 25944					
Date <u>December 20, 2005</u>			NAME: James A. Oliff REGISTRATION NUMBER: 27,075  NAME: Jesse O. Collier REGISTRATION NUMBER: 53,839		

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Yukinori MASUDA et al.

Application No.: 10/549,510

Filed: September 20, 2005

Docket No.: 125413

For: T-TYPE CALCIUM CHANNEL BLOCKER

INFORMATION DISCLOSURE STATEMENT

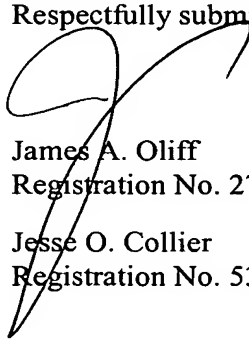
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR §1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

- ☒ 1. This Information Disclosure Statement is being filed (a) within three months of the U.S. filing date of this non-CPA application, OR (b) before the mailing date of a first Office Action on the merits in the present application. No certification or fee is required.
- ☒ 2. Relevance of references 2-8 and 11-20 is discussed in the present specification.
- ☒ 3. References 10-11 were cited in the International Search Report. An English language version of the International Search Report is attached for the Examiner's information.
- ☒ 4. In accordance with 37 CFR §1.98(a)(2)(ii), copies of any U.S. patents and patent application publications are not attached.
- ☒ 5. English language Abstracts of the non-English language references are attached hereto.
- ☒ 6. Reference 9 corresponds to JP-A-05-194393, which is cited on the International Search Report; a copy of the Japanese language reference is not attached.

Respectfully submitted,

  
James A. Oliff  
Registration No. 27,075

Jesse O. Collier  
Registration No. 53,839

JAO:JOC/nxy

Date: December 20, 2005

**OLIFF & BERRIDGE, PLC**  
**P.O. Box 19928**  
**Alexandria, Virginia 22320**  
**Telephone: (703) 836-6400**

**DEPOSIT ACCOUNT USE  
AUTHORIZATION**

Please grant any extension  
necessary for entry;  
Charge any fee due to our  
Deposit Account No. 15-0461

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 125413		APPLICATION NO. 10/549,510	
INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)				APPLICANTS Yukinori MASUDA et al.			
				FILING DATE September 20, 2005		GROUP	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
	1.	4,885,284	12/05/1989	Kiyotomo SETO et al.			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
	2.	JP-A-61-030591 w/ abst.	02/12/1986	JAPAN			
	3.	JP-A-60-069089 w/ abst.	04/19/1985	JAPAN			
	4.	JP-A-01-275591 w/ abst.	11/06/1989	JAPAN			
	5.	JP-A-61-063688 w/ abst.	04/01/1986	JAPAN			
	6.	JP-A-63-233992 w/ abst.	09/29/1988	JAPAN			
	7.	JP-A-62-169795 w/ abst.	07/25/1987	JAPAN			
	8.	JP-A-62-169796 w/ abst.	07/25/1987	JAPAN			
	9.	EP 0 500 426 A1	08/26/1992	EUROPEAN PATENT OFFICE			
	10.	WO 01/04124 A1	01/18/2001	WIPO			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)							
	11.	Haruko MASUMIYA et al.; "Effects of Ca <sup>2+</sup> channel antagonists on sinus node: Prolongation of late phase 4 depolarization by efonidipine"; <i>European Journal of Pharmacology</i> ; Vol. 335; 1997; pp. 15-21.					
	12.	Paul MULDER et al.; "Increased Survival After Long-Term Treatment with Mibefradil, a Selective T-Channel Calcium Antagonist, in Heart Failure"; <i>JACC</i> ; Vol. 29, No. 2; February 1997; pp. 416-421.					
	13.	Johanne VILLAME et al.; "Effects of Mibefradil, a T- and L-Type Calcium Channel Blocker, on Cardiac Remodeling in the UM-X7.1 Cardiomyopathic Hamster"; <i>Cardiovascular Drugs and Therapy</i> ; Vol. 15; 2001; pp. 41-48.					
	14.	Samir FAREH et al.; "The T-Type Ca <sup>2+</sup> Channel Blocker Mibefradil Prevents the Development of a Substrate for Atrial Fibrillation by Tachycardia-Induced Atrial Remodeling in Dogs"; <i>Circulation</i> ; Vol. 100; November 23, 1999; pp. 2191-2197.					
EXAMINER					DATE CONSIDERED		
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Date: December 20, 2005

Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 125413		APPLICATION NO. 10/549,510	
INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)				APPLICANTS Yukinori MASUDA et al.			
				FILING DATE September 20, 2005		GROUP	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)							
	15.	Georg NOLL et al.; "Comparative Pharmacological Properties among Calcium Channel Blockers: T-Channel versus L-Channel Blockade"; Cardiology; Vol. 89; Supp. 1; 1998; pp. 10-15.					
	16.	Chris BAYLIS et al.; "Comparison of L-Type and Mixed L- and T-Type Calcium Channel Blockers on Kidney Injury Caused by Deoxycorticosterone-Salt Hypertension in Rats"; <i>American Journal of Kidney Diseases</i> ; Vol. 38, No. 6; 2001; pp. 1292-1297.					
	17.	D. BILICI et al.; "Protective Effect of T-Type Calcium Channel Blocker in Histamine-Induced Paw Inflammation in Rat"; <i>Pharmacological Research</i> ; Vol. 44, No. 6; 2001; pp. 527-531.					
	18.	Sebastien LENGLET et al.; "Activation of 5-HT <sub>7</sub> Receptor in Rat Glomerulosa Cells is Associated with an Increase in Adenylyl Cyclase Activity and Calcium Influx through T-Type Calcium Channels"; <i>Endocrinology</i> ; Vol. 143, No. 5; pp. 1748-1760.					
	19.	J. Bruce MCCALLUM et al.; "Loss of T-type Calcium Current in Sensory Neurons of Rats with Neuropathic Pain"; <i>Anesthesiology</i> ; Vol. 98, No. 1; 2003; pp. 209-216.					
	20.	Darrell M. PORCELLO et al.; "Actions of U-92032, a T-Type CA <sup>2+</sup> Channel Antagonist, Support a Functional Linkage Between I <sub>T</sub> and Slow Intrathalamic Rhythms"; <i>Journal of Neurophysiology</i> ; Vol. 89; January 2003; pp. 177-185.					
EXAMINER				DATE CONSIDERED			
Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Date: December 20, 2005